

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
DEPARTMENT OF PESTICIDE REGULATION

MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA  
PHENMEDIPHAM

Chemical Code # 000675, Tolerance # 00278

SB 950 # 211

Original date: March 8, 2000

Revised: 1/24/03; 9/18/03

I. DATA GAP STATUS

Chronic toxicity, rat:	Data gap, inadequate study, no adverse effects indicated
Chronic toxicity, dog:	Data gap, in adequate study, no adverse effects indicated
Oncogenicity, rat:	Data gap, inadequate study, no adverse effects indicated.
Oncogenicity, mouse:	No data gap, no adverse effects
Reproduction, rat:	Data gap, inadequate study, no adverse effects indicated.
Teratology, rat:	No data gap, no adverse effects
Teratology, rabbit:	No data gap, no adverse effects
Gene mutation:	No data gap, no adverse effects
Chromosome effects:	No data gap, no adverse effects
DNA damage:	No data gap, no adverse effect
Neurotoxicity:	Not required at this time

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Toxicology one-liners are attached.

All record numbers through 075 205300 were examined.

\*\* indicates an acceptable study.

**Bold face** indicates a possible adverse effect.

File Name: T030918

Toxicology Summary Prepared by Kishiyama & Silva, 3/8/00, Silva, 1/24/03; Silva, 9/18/03

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

## CHRONIC TOXICITY, RAT

### Chronic Study:

025, 028 014836, 0145519 "Phenmedipham: 104-Week Chronic Toxicity Study in Male and Female Rats," (Frederick E. Reno, Director, Hazleton Laboratories America, Report No. 947-103, 11/25/80).

Phenmedipham technical (purity not given) was fed in diet ppm to Sprague-Dawley rats (60/sex/dose) at 0, 20, 100, or 500 for 104 weeks. UNACCEPTABLE. There were insufficient data (hematological/clinical biochemistry) performed on too few animals. The study lacked data on eye examination, individual data, detailed daily observations, a description of which organs and tissues were examined; appendices not included, analysis of dosing solution and purity of test article. (J. Wong, 6/6/85). This DPR Volume/record (278 - 028/045519) with appendices was evaluated in light of the previous submission (278 - 025/014836) and it remains UNACCEPTABLE. The study continues to lack a justification for dose selection, ophthalmological examination and an insufficient number of rats examined for clinical pathology. An MTD was not achieved. NOEL > 500 ppm. (Kishiyama & Silva, 3/8/00).

### Subchronic:

**\*\* 278 - 075 205300** "Phenmedipham 90-Day Toxicity Study in the Rat by Dietary Administration," (Foulon, O.; Aventis CropScience (currently BayerCrop Science, Research Triangle Park, NC); Report #: SA 00397; 3/21/02; Submitted under 6(a)(2) of FIFRA, based on criterion #11). Phenmedipham technical (98.4% pure) was fed in diet to Wistar (AF) RJ: WI(IOPS HAN) rats (10/sex/dose) at 0, 1000, 3000, 10 000 and 20 000 ppm for 90 days. NOEL < 1000 ppm (Body weights were statistically significantly decreased at  $\geq 3,000$  ppm in males and at  $\geq 10,000$  ppm in females. Food consumption in both sexes at  $\geq 3,000$  was statistically significantly decreased. Females had a higher mean urinary volume at  $\geq 10,000$  ppm and a lower mean refractive index at 20,000 ppm. In both sexes there were effects on hematology, including anisochromia and anisocytosis with macrocytosis at  $\geq 1000$  ppm. There were statistically significant clinical chemistry effects in both sexes at  $\geq 1000$  ppm. At 20,000 ppm 6/10 males and 2/10 females had dark livers. The decreased terminal bodyweights at  $\geq 10,000$  ppm, the statistically significant increase in absolute liver weights in females and increased absolute spleen weights in males were considered treatment-related. There were, however, many affected organ weights in both sexes at  $\geq 1000$  ppm. Hepatocellular hypertrophy (diffuse centrilobular) was increased in males at 20,000 ppm and in females at  $\geq 10,000$  ppm. There was an increase in golden brown pigment, primarily in Kupffer cells (diffuse) in liver at  $\geq 1000$  ppm in both sexes. In adrenals, the severity of diffuse vacuolation in the zona fasciculata was increased in a dose-related manner in all treated males. In spleen, at  $\geq 3000$  ppm, the severity of multifocal/diffuse hemosiderin pigmentation and extramedullary hematopoiesis was increased in both sexes (females  $\geq$  at 1000 ppm.) Acceptable. Possible adverse effects: increased incidence in effects in body weight gain, liver, blood and spleen. M. Silva, 9/11/03

**\*\* 049 115443**, "Phenmedipham: Three-Month Subchronic Oral Toxicity Study in Rats", (K. Kojima & M. Enomoto, Biosafety Research Center (An-PYO Center), Japan, Exp. No. 50, 5/31/81). Phenmedipham (purity = 98.6%) was fed in diet at 0, 50, 500 and 5000 ppm to Fischer F 344 rats

(20/sex/dose) for 13 weeks. NOEL = 50 ppm; M: 3.5 mg/kg/day; F: 3.7 mg/kg/day (Body weights and food consumption were statistically significantly decreased in both sexes at 5000 ppm. HGB and HCT decreased in males at  $\geq 500$  ppm and in females at 5000 ppm. RBC decreased at  $\geq 500$  ppm in both sexes. Platelets and WBC were increased in males at 5000 ppm. An increase in cholesterol, LDH, total protein and bilirubin in both sexes at 5000 ppm was induced. SGPT and glucose were increased in females (5000 ppm). Blood urea nitrogen (BUN) was slightly decreased in females at  $\geq 500$  ppm. Cholinesterase activities were increased slightly in both sexes at all doses (Urine volume decreased, specific gravity increased and color deepened at  $\geq 500$  ppm in females. Liver (5000 ppm) and spleen ( $\geq 500$  ppm) weights were increased in both sexes. Testes and adrenal weights were increased for males at 5000 ppm. Histology: An increased incidence of enlarged black colored spleen occurred in both sexes at 5000 ppm. Increased incidence of hematopoiesis of the bone marrow was reported in both sexes at 5000 ppm.) No adverse effect. Acceptable. (Kishiyama & Silva, 2/23/00).

### CHRONIC TOXICITY, DOG

025, 027 014835, 045518 "Phenmedipham: 104-Week Chronic Toxicity Study in Dogs," (Marshall, P.M., Hazleton Laboratories America, Inc., Vienna, VA; Report No. 947-104; 6/12/80). Phenmedipham technical (purity assumed 100%) was fed in diet to Beagle dogs (8/sex/dose) at 0, 40, 200 or 1000 ppm for 104 weeks. No evidence of treatment related effects. NOEL = 1000 ppm/day (No effects at any dose, as stated in the report). In a previous DPR review (Wong, 6/6/85) this study (DPR Volume/record #: 278-025/014835) was UNACCEPTABLE (insufficient information for assessment). The current study (a duplicate of the previous submission plus some of the requested data) remains unacceptable (no MTD; report lacks justification for dose selection) and not upgradeable. Insufficient data to assess the possibility of an adverse effect. (Kishiyama & Silva, 2/25/00).

### ONCOGENICITY, MOUSE

\*\* 036 & 050 069362 & 115447 (Addendum 5) "Technical Phenmedipham: Oncogenicity Study in the Mouse by Dietary Administration," (Crome, S.J., V. Stuart, D. Crook, W.A. Gibson, R.S. Rao, and C. Gopinath; Huntingdon Research Centre, Huntingdon, Laboratory Project ID TOX 84078; 12/16/87). Phenmedipham Technical (purity = 99.3%) was fed in diet to CD-1 mice (52/sex/dose) at 0, 10, 100, or 1,000 ppm for 102-104 weeks. Systemic NOEL = 100 ppm ;M: 11.0 mg/kg; F: 12.0 mg/kg (Kidney weight increased in both sexes at 1000 ppm (no accompanying histopathology) Incidence of masses and pale areas of the liver was increased and cystic ovaries and cystic uteri were decreased in females at 1000 ppm.) No evidence of oncogenicity reported. MTD, although equivocal for this study is based on a previous range-finding (050 115448) study. ACCEPTABLE. No adverse effect. (Kishiyama & Silva, 2/29/00).

036 (part 2, volume 2) 069363, "Determination of Phenmedipham Dietary Concentrations for a 2 Year Dietary Oncogenicity Study in the Mouse", (J.H.M. Bright, Schering Agrochemicals Limited, West Germany, Study No. Tox 84078, Report No. RESID/87/51, 9/10/87). Technical phenmedipham (batch 331684) concentrations of 10, 100 and 1,000 ppm were analyzed for concentration, homogeneity and stability in rodent diet (Spratt's Laboratory animal diet No. 2) for the current, definitive mouse oncogenicity study (DPR Volume/record #: 036/069362). High performance liquid chromatography was used to analyze the concentration of methanol extracted phenmedipham. Analyses for concentration of phenmedipham in samples at approximately weekly

intervals averaged 105.9, 98.8 and 99.8% of nominal at 10, 100, and 1,000 ppm, respectively. Homogeneity samples were taken from the top, middle and bottom portions at 10, 1000 and 1,000 ppm dietary mixtures and varied approximately 2.5%, 2.3% and 3.4%, respectively. After 21 days, analyses for stability showed concentrations averaged 100.1, 99.7 and 100.6% of nominal at 10, 100 and 1,000 ppm, respectively. (Kishiyama & Silva, 2/29/00).

050 115448 & 115450, "T87 Technical Phenmedipham: 8 Week Dietary Study in the Mouse," (G.K. Lloyd; Huntingdon Research Centre, England, HRC TOX/85/129-5, FBC TOX/84077, 12/15/85). Technical Phenmedipham (purity = 99.3%) was fed in diet to Swiss CD-1 mice (60/sex/dose) at 0, 1000, 5000, 15000 ppm for 8 weeks. NOEL = 1000 ppm; M: 125 mg/kg; F: 144 mg/kg (Methemoglobin levels increased at  $\geq 5000$  ppm (both sexes). Liver weights were increased at  $\geq 5000$  (both sexes). Spleen weights were increased in males at 15000 ppm. Spleen enlargement was observed in both sexes at 15000 ppm. Prominent germinal centers of the spleen were observed (microscopically) for males at  $\geq 5000$  ppm and females at 15000 ppm. Brown pigment in liver Kupffer cells was observed for 65% and 100% of animals at  $\geq 5000$  ppm (both sexes). Incidence of extramedullary hemopoiesis was increased for high dose males. No adverse effect. These data are supplemental. (Kishiyama & Silva, 2/29/00).

050 115450. Supplement to 115448. Diet Analysis. (Kishiyama & Silva, 3/9/00)

## REPRODUCTION, RAT

001, 051 028490, 115453, 115456, 115458 "Phenmedipham: A Three-Generation Reproduction and Teratology Study in Rats," (Kapp, R.W., Dawkins, K.K. & Mossburg, P.A.; Hazleton Laboratories America, Inc., Vienna, VA; Hazleton and Schering Project #: 947-105; Report #: T26;7/5/79). Phenmedipham technical (98.4% pure) was fed in diet to Sprague-Dawley, CD<sup>®</sup> rats (15 males & 30 females/dose) at 0, 20, 100 and 200 ppm for 3 generations (2 litters/generation). Maternal NOEL > 500 ppm (There were no reproductive effects observed at any dose.) Parental Systemic NOEL > 500 ppm (There were no treatment-related effects at any dose.) Pup NOEL > 500 ppm (There were no significant treatment-related effects in pups at any dose. This study was previously reviewed by Wong (6/5/85) as unacceptable. Upon re-review, it remains unacceptable and not upgradeable. There were too many deficiencies and it was performed in conjunction with a teratology study. M. Silva, 3/14/00.

074 179471 "Two-Generation Reproduction Toxicity Study with Phenmedipham T.O.P. techn. Sample in Rats (3<sup>rd</sup> addendum to MRID No. 44862702; Company No. C98701)," (McAnulty, P.A., Scantox DK, Skensved, Denmark; Study #: 10600, 12/12/00). This volume contains tables, figures and appendices (individual data) for F0 and F1 generation body weight and lactation during gestation and lactation. Appendices V through VIII was individual data for parental F0 and F1 clinical signs and F1 and F1 offspring clinical signs and observations of offsprings killed day 4. No worksheet. M. Silva, 1/24/03.

## TERATOLOGY, RAT

\*\* 052 115462 & 115463, "T126 Phenmedipham Technical: Embryotoxicity Study (including teratogenicity) with Phenmedipham Technical in the Rat," (P.A. Allen, D. Frei, P. Mladenovic & Ch.

Terrier; RCC Research and Consulting Company AG, Iringen, Switzerland; RCC Proj. 095782; 10/5/88). Phenmedipham technical (purity = 97.8%) was administered by gavage to mated female Wistar rats (25/dose) at 0 (distilled water with 4% CMC), 150, 450 and 1350 mg/kg (limit test for developmental toxicity = 1000 mg/kg) during gestation days 6 – 15. Developmental NOEL  $\geq$  1350 mg/kg. Maternal NOEL = 450 mg/kg/day (There was a slight decrease in bodyweight gain at 1350 mg/kg/day.) Acceptable. No adverse effect indicated. (Kishiyama & Silva, 3/1/00).

052 115463. Supplement to 115462. Tabulation of skeletal variations.

001 028489 "Three-Generation Reproduction and Teratology Study in Rats - Phenmedipham, Final Report," (Mossburg, P.A.; Hazleton Laboratories America Inc., Vienna, VA; Project #: 947-103; 7/5/79). Phenmedipham (purity not stated; assumed 100%) was fed in diet to mated Sprague-Dawley rats (15/dose) at 0, 20, 100 or 500 ppm. Treatment period was not stated in the report, however since this study was combined with a reproduction study, treatment was assumed to be throughout gestation. UNACCEPTABLE (major variances from FIFRA Guidelines; insufficient information; dose justification). Not upgradeable. The deficiencies were too numerous for this study to be upgraded. (J. Wong, 6/5/85).

### TERATOLOGY, RABBIT

\*\* 055 129352 "T169/2 Technical Phenmedipham: Rabbit Oral Developmental Toxicity (Teratogenicity) Study with Appendix 1: A Preliminary Study of the Effect of Technical Phenmedipham on Pregnancy of the Rabbit," (Jones, K., C. Brennan & D. John; Huntingdon Research Centre, Ltd., England; Laboratory Project ID #: TOX 91093; 9/10/92). Phenmedipham technical (purity = 99.3%) was administered by gavage to mated New Zealand White female rabbits (16 – 21/dose) at 0 (1% methylcellulose in distilled water), 5, 71 or 1000 mg/kg during gestation days (gd) 6 through 18. Food consumption and body weight change were decreased at 1000 mg/kg. Maternal NOEL = 71 mg/kg/day. There were no effects on fetal development at any dose. Developmental NOEL = 1000 mg/kg/day. No adverse effect. ACCEPTABLE. (Kishiyama & Silva, 3/1/00).

025 014841 "Embryotoxicity Study in Rabbits after Daily Administration by Stomach Tube During Days 6 - 8 of Gestation," (Poggel, H.A.; Schering Agrochemicals Limited, Berlin, Germany; Report #: PF; 1/24/78). Phenmedipham (purity not stated) was administered via gavage to mated New Zealand White rabbits (13-15/dose) at 0, 5, 50 and 500 mg/kg during gestation days 6 through 18. UNACCEPTABLE (major variances from FIFRA Guidelines; insufficient information). Not upgradeable (Too many deficiencies to correct.) (J. Wong, 6/5/85).

**026 034960:** Same study as 025 014841. ZK. 15.320 Embryotoxicity Study in Rabbits after Daily Administration by Stomach Tube During Days 6 - 8 of Gestation (Phenmedipham). Schering Agrochemicals Limited, Berlin, Germany. 1/24/78. Phenmedipham, purity not stated, at concentrations of 5, 50 and 500 mg/kg was evaluated for teratogenic effects on rabbits. No evidence of maternal toxicity. **Possible adverse effects: visceral anomalies in all treated groups.** UNACCEPTABLE (major variances, insufficient information). Not upgradeable. (J. Parker, 9/16/85).

### GENE MUTATION

035 069359, "T106-Phenmedipham: Mutagenicity Evaluation of Phenmedipham Technical in the HGPRT Forward Mutation Assay," (W.C. denBoer & A.J.W. Hoorn; Hazleton Biotechnologies Veenendaal Laboratory, The Netherlands, Lab. ID No. PF - 86.829, 3/27/87). Technical Phenmedipham (purity = 98.6%) was used on Chinese Hamster V79 cells at 0 (DMSO), 50, 75, 100, 125, 150 µg/ml (+S-9 mix) and at 0, (DMSO), 75, 100, 125, 150, or 200 µg/ml (no S-9 mix) to assess mutagenicity at the HGPRT locus after a 4 hour exposure. Mutation frequency, although statistically significantly increased, relative to controls, the report stated phenmedipham was nonmutagenic. However, results were equivocal and the test should have been repeated to determine whether or not phenmedipham was mutagenic. UNACCEPTABLE (no repeat test; no analysis of dosing material for homogeneity & content). (Kishiyama & Silva, 2/2/00).

\*\* 053 115464, "T114 Phenmedipham: Mutagenicity Test on Phenmedipham Technical in the Ames Salmonella/Microsome Reverse Mutation Assay," (A.J.W. Hoorn; Hazleton Biotechnologies, The Netherlands, Lab Project ID E-9705-0-401, 9/7/87). Phenmedipham technical (purity = 98.3%) was used on *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA98 and TA100 at 0, 1, 10, 100, 500, 1000, 2500, 5000 and 10000 µg (3 plates/dose) to test for mutagenic potential. Two trials were performed. Phenmedipham dose levels 10000 and 5000 µg/plate were highly toxic and 2500 µg/plate moderately toxic to *Salmonella* strains. There was no evidence of a treatment-related increase in reverse mutation. The positive controls performed as expected. No adverse effect. ACCEPTABLE. (Kishiyama & Silva, 3/7/00).

026 034958 "Further Mutagenicity Studies on Pesticides in Bacterial Reversion Assay Systems," (Schering Agrochemicals Limited; 7/16/82). Phenmedipham (no purity stated) was evaluated for mutagenicity using *Salmonella typhimurium* strains TA98, TA100 TA1535, TA1537, and TA1538; and *Escherichia coli* strain WP2 hcr with and without metabolic activation (S9 Mix). UNACCEPTABLE (insufficient information). (A. Apostalou; 9/16/85).

026 034959 "Genetic Effects of Herbicides: Induction of Mitotic Gene Conversion in *Saccharomyces cerevisiae*," (Schering Agrochemicals Limited; 1974). Phenmedipham (no purity stated) at a concentration of 0 and 1000 ppm (no S9) was evaluated for inducing mitotic gene conversion in *Saccharomyces cerevisiae*. UNACCEPTABLE (insufficient information, major variances from FIFRA Guidelines). Not upgradeable. (A. Apostalou, 9/16/85).

025 014833 "Mutagenicity of Diallate, Sulfallate, and Triallate and Relationship Between Structure and Mutagenic Effects of Carbamates Used Widely in Agriculture," (DeLorenzo, F., Staiano, N., Silengo, L. & Cortese, R.; Cancer Research, 38:13-15, 1/ 78). Phenmedipham (no purity stated) was screened for mutagenicity with 20 other carbamate herbicides and fungicides using *Salmonella typhimurium* strains. UNACCEPTABLE (Insufficient information). (J.Wong, 6/6/85).

025 014838 "Testing for Mutagenic Activity of ZK 15,320," (Glass, E.J., Hastwell, R.M. & McGragor, D.B.; Inversek Research International, Edinburg, Scotland; Report No. 616; 10/76). Phenmedipham (no purity stated) at 0 (DMSO), 5, 25, 125, 500, or 2,500 µg/plate were assayed on *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538. UNACCEPTABLE (major variances from FIFRA Guidelines: 1 plate/dose/strain, no positive controls without S9, purity of test substance not reported). Not upgradeable. (J. Wong, 6/5/85).

\*\* 025 014834 "Phenmedipham: Microbial Mutagenicity Study," (Shirasu, Y.; Institute of Environmental Toxicology Tokyo, Japan; 6/80). Phenmedipham (99.6% pure) at 0, 1, 5, 10, 50, 100, 500, 1000 and 5000 µg/plate was evaluated for mutagenicity using *Salmonella typhimurium* strains TA 98, TA100, TA1535, TA1537 and TA1538 (+/- S9 mix). In addition, a rec assay with *Bacillus subtilis* strains M45 and H17 was performed at 0, 20, 100, 200, 500, 1000 and 2000 ug/disk in a spot test. No evidence of mutagenicity reported. ACCEPTABLE (with minor deficiencies). (J. Wong, 6/6/85).

## CHROMOSOME EFFECTS

\*\* 035 069360 "T106-Phenmedipham: Clastogenic Evaluation of Phenmedipham Technical in an *In Vitro* Cytogenetic Assay Measuring Chromosomal Aberration Frequencies in Whole Blood Human Lymphocytes (final report)," (R.Taalman & A. Hoorn; Hazleton Biotechnologies Veenendaal Laboratory; The Netherlands, Laboratory Project No. E-9578; 2/87). Phenmedipham technical (purity = 98.6%) at 0 (DMSO and untreated cells), 2.5, 5.0, 10.0, or 25.0 µg/ml (no S9 mix) for 46.25 - 48.55 hours and at 50, 100, 200 or 400 µg/ml (+ S9 mix) for 1 hour were assayed on human lymphocytes in whole blood from a single donor (sex not specified) for chromosome aberrations (only 1 adequate trial  $\pm$  S9 reported; duplicate cultures/dose). Total culture time was approximately 72 hours before harvest. Phenmedipham treatments did not induce cellular aberrations. ACCEPTABLE (with minor deficiencies). No adverse effect. (Kishiyama & Silva, 3/3/00).

025 014840, "Testing for Mutagenic Potential of ZK 15,320 after Two Intragastric Administration to Male and Female Mice in the Micronucleus Test," (Lang, R.; Schering AG, Berlin, Germany, 5/19/78). Phenmedipham (no purity stated), administered by gavage to NMRI/Kisslegg mice (5 /sex/dose) at 0, 100, 300, or 1,000 mg/kg, in 2 administrations at 24 hour intervals. UNACCEPTABLE due to major variances in FIFRA Guidelines (no dose justification, no actual counts, no criteria for scoring micronucleus, no analysis of dosing solution, no purity given for test article and no QA sign-off). (J. Wong, 6/5/85).

050 115452, "T18 Phenmedipham: Testing for Mutagenicity Potential of ZK 15.320 after Two Intragastric Administration to Male and Female Mice in a Micronucleus Test," (Roskamp; Schering AG, Federal Republic of Germany, Lab. Proj. I.D. 316/77, 5/19/78). ZK 15 320 (purity not stated) was administered by gavage (twice, 24 hours apart) to SPF NMRI mice (5/sex/dose) at 0 (0.9 g NaCl, 0.085 g Myrj 53 in 100 ml Aqua bidest), 100, 300 or 1000 mg/kg. Femoral bone marrow smears were prepared 6 hours after the second treatment. ZK 15 320 treatments failed to show evidence of cytotoxicity or increased numbers of micronucleated polychromatic erythrocytes. UNACCEPTABLE. Not upgradeable (study lacks: justification for dose selections, test article purity, dosing material analysis, no sign of cytotoxicity in bone marrow, individual data and inadequate number of sampling periods for bone marrow). (Kishiyama & Silva 2/2/00). This study was also considered UNACCEPTABLE in an earlier review (DPR Volume/record #: 025/014840) by J. Wong, 6/5/85.

## DNA DAMAGE

\*\* 035 069361 "T106-Phenmedipham: Mutagenicity Test on Phenmedipham Technical in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay," (Cifone, M.A.; Hazleton Laboratories America, Inc.; HLA Study #: 9947-0-447; Schering Project #: TB 87034;12/11/87). Phenmedipham technical (purity = 98.3%) was used on primary rat hepatocytes at 0 (DMSO), 2.5, 5.0, 10.0, 25.0, 37.5, or 50.0 µg/ml to detect DNA damage (2 cultures/dose for cytotoxicity & 3/dose for UDS). Phenmedipham did not induce detectable DNA damage/repair in the test system. There was no treatment-related increase in DNA unscheduled synthesis (UDS) at any dose. Positive controls functioned as expected. ACCEPTABLE with minor deficiencies. No adverse effect. (Kishiyama & Silva, 3/7/00).

\*\* 025 014834 "Phenmedipham: Microbial Mutagenicity Study," (Shirasu, Y.; Institute of Environmental Toxicology, Tokyo, Japan; 6/80). Phenmedipham (99.6% pure) was evaluated for genotoxic potential at 0, 1, 5, 10, 50, 100, 500, 1000 and 5000 µg/plate (+/- S9 mix), using *Bacillus subtilis* rec (H17/M45) and *Escherichia coli* WP2 hcr. The *Bacillus subtilis* assays were not acceptable (major variances from FIFRA Guidelines). The *Escherichia coli* assays were ACCEPTABLE (with minor variances). No evidence of mutagenicity was observed. (J. Wong, 6/6/85).

### MISCELLANEOUS TESTS/ASSAYS

025 014842 "Mutagenicity Screening of Pesticides in the Microbial System," (Shirasu, Y., Moriya, M., Furuhashi, A. & Kada, T.; Institute of Environmental Toxicology, Tokyo, Japan & National Institute of Genetics, Mishima, Japan; published in Mutation Research, 40:19-30, 1976). Phenmedipham (no purity stated) was used in a rec-assay with *Bacillus subtilis* (strains: H17 Rec<sup>+</sup> & M45 Rec<sup>-</sup>) and in reverse mutation assays with *Salmonella typhimurium* (strains: TA1535, TA1536, TA1537 & TA1538) and *Escherichia coli* (strains: WP2 & WP2 try her). Phenmedipham was evaluated with 166 pesticides in the report. All tests were "spot" tests. This was not a FIFRA Guideline study. Phenmedipham was not positive in any of the tests performed in this report. No adverse effects. These data are supplemental. (J. Wong, 6/5/85).